UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,631	08/05/2003	Ellen M. Beasley	CL001078DIV	6370

25748 7590 02/16/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
45 WEST GUDE DRIVE
C2-4#20
ROCKVILLE, MD 20850

EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,631	BEASLEY ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-3 and 10-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Given the Preliminary Amendment filed by Applicant on August 5, 2003 to cancel Claims 4-9 and 22-23, Claim 13 (identified as Group VIII below) is incomplete and cannot be properly assessed for restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 10, 11, 20 and 21, drawn to an isolated peptide of amino acid sequence shown in SEQ ID NO:2, either full-length, allelic variant, ortholog or fragment thereof, and a method for producing said peptides in a host cell, classified in class 530, subclass 327 and 350.

II. Claim 3, drawn to an isolated antibody that selectively binds to a peptide of Group I, classified in class 424, subclass 178.1.

III. Claims 16 drawn to a method for identifying an agent that binds to any of the Group I peptides, classified in class 435, subclass 7.1.

IV. Claim 12, drawn to a method for detecting the presence of any of the Group I peptides using a detection agent, classified in class 435, subclass 7.1.

V. Claims 14 and 15, drawn to a method for identifying a modulator of a Group I peptide, whereby an agent that contacts said peptide is administered to a host cell comprising an expression vector that expresses said peptide, classified in class 435, subclass 7.1.

VI. Claim 19, drawn to a method of identifying a modulator of the expression of a Group I peptide, classified in class 435, subclass 7.1.

VII. Claim 17 and 18, drawn to a pharmaceutical composition comprising an agent identified by Group III and a pharmaceutically acceptable carrier thereof and a method for treating disease or condition mediated by a human kinase protein, wherein a pharmaceutically effective amount of an agent is administered to a patient, classified in class 977, subclass 904 and 915.

VIII. Claim 13, drawn to a method for detecting the presence of a nucleic acid of Claim 5 using an oligonucleotide, classified in class 530, subclass 287.2.

Inventions of Groups I and III-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Group I is drawn to an isolated peptide of amino acid sequence shown in SEQ ID NO:2, either full-length, allelic variant, ortholog or fragment thereof and a method for producing said peptide in a host cell. Group III is drawn to a method to identify an agent that binds to a Group I peptide. Group IV is drawn to a method for detecting the presence of a Group I peptide. Group V is drawn to a method to identify a modulator of a Group I peptide. Group VI is directed to a method for identifying a modulator of Group I peptide expression. The activity of Group I peptides does not require the agents identified by the Group III-VI methods to be useful, and thus is independent of those agents. Each Group III-VI method invention comprises the use of separate products and techniques in order to achieve its respective and intended objective. With these inventions, Applicant will identify agents of unknown composition. Such agents may be a polypeptide, a nucleotide or a chemical compound (and derivatives thereof, respectively) and thus have materially different design and effect. A binding agent identified by the invention of Group III may not be useful for detection as sought by Group IV, would not necessarily

modulate a Group I peptide's activity as sought by the invention of Group V, nor would it necessarily effect decreased expression of a Group I peptide as sought by the invention of Group VI. Each agent that does bind the Group I target peptide may well bind through different means, at different locations along said peptide and have different effects on the Group I peptide's activity, and thus each binding agent is not an obvious variant of the other. Furthermore, an agent that affected the transcription of a Group I peptide gene or the translation of a Group I peptide messenger RNA would not necessarily be expected to fulfill the activities sought by Group III, VI and V. Therefore, the inventions of Group III, IV, V and IV are mutually exclusive and patentably distinct. Present Claim 12, 14, 16 and 19 relate to an extremely large number of possible compounds/products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. A search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims.

Because these inventions are independent and distinct for the reasons given above and a search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

The invention of Group I is unrelated to Groups II and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group I is drawn to an isolated peptide of amino acid sequence shown in SEQ ID NO:2, either full-length, allelic variant, ortholog or fragment thereof and a method for producing said peptide in a host cell. Group II is drawn to an isolated antibody that selectively binds to a Group I peptide. Group VII is drawn to a pharmaceutical composition comprising an agent that binds to any of the Group I peptides and a pharmaceutically acceptable carrier therefor to be administered to a patient for use in treating disease or condition mediated by a human

kinase protein. Applicant defines an antibody in terms consistent with that recognized in the art. It is understood that an antibody binds to its target molecule by recognizing a specific epitope on the target molecule. The effect of said antibody on the target molecule is dependent upon the location of the epitope. As such, not all antibodies that recognize a target molecule will inhibit or obstruct the target molecule's activity or effect. The Group I peptide is the claimed target molecule of the Group II antibody, and as such both Group I and Group II are mutually exclusive of each other. The composition of the agent in Group VII is unknown. Such an agent may be a polypeptide, a nucleotide or a chemical compound (and derivatives thereof, respectively) and thus have materially different structure. Each binding agent required by Claim 16 is not an obvious variant of the other. Each molecule may well bind the target Group I peptide through different means, at different locations along said peptide and have different effects on the Group I peptide. The Group I peptide is the claimed target molecule of the pharmaceutical agent of Group VII, and as such both Group I and Group VII are mutually exclusive of each other. Present Claim 16, and therefore Claim 17, relates to an extremely large number of possible compounds/products. In the present case, the claim so lacks support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Because these inventions are independent and distinct for the reasons given above and a search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions. (See M.P.E.P. § 802.01.)

Groups II and VII are directed to products that are mutually exclusive, are not obvious variants and can have a materially different design or effect, and are therefore patentably distinct. In the instant case, Applicant defines an antibody in terms consistent with that recognized in the

art, and it is understood that an antibody binds to its target molecule by recognizing a specific epitope on the target molecule. The effect of said antibody on the target molecule is dependent upon the location of the epitope. As such, not all antibodies that recognize a target molecule will inhibit or obstruct the target molecule's activity or effect. Although the antibody of Group II does meet the criteria of Group VII, molecules of materially different structure can also satisfy Claim 17. Such an agent may be another polypeptide, a nucleotide or a chemical compound (and derivatives thereof, respectively). Each molecule may well bind the target peptide of Group I through different means, at different locations along said peptide and have different effects on the Group I peptide. Thus each class of binding agent is not an obvious variant of the other.

Because these inventions are independent and distinct for the reasons given above and a search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Inventions of Group III, IV, V, VI and Group VII are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Products obtained by the methods of Groups III, IV, V and VI may be a polypeptide, a nucleotide or a chemical compound (and derivatives thereof, respectively). These agents have materially different design and effect, yet will fulfill the criteria for use in invention of Group VII, thus directly illustrating that the product claimed in Group VII can be made by another and materially different process. Present Claim 12, 14, 16 and 19 relate to an extremely large number of possible compounds/products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Because these inventions are distinct for the reasons given above and a search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it

would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Inventions of Groups III-VI and Groups II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, Applicant defines an antibody in terms consistent with that recognized in the art: they are multi-subunit proteins produced by mammalian organisms in response to an antigenic challenge. An isolated antibody may either be monoclonal or polyclonal. It is understood that a monoclonal antibody binds to its target molecule by recognizing a specific epitope on the target molecule. Polyclonal antibodies are in fact a population of antibodies that recognize the target molecule. Although each particular antibody recognizes its own specific epitope, the polyclonal nature results in several epitopes of the target molecule being recognized simultaneously by the polyclonal antibody. The antibody's effect on the target molecule is dependent upon the location of the epitope. Not all antibodies that recognize a target molecule will inhibit or obstruct the target molecule's activity or effect. Although the antibody of Group II does meet the criteria of Groups III-VI, molecules of materially different structure and function can also satisfy the purposes of Claims 12, 14, 16 and 19. Such an agent may be another polypeptide, a nucleotide or a chemical compound (and derivatives thereof, respectively). Each molecule may well bind the target peptide of Group I through different means, at different locations along said peptide and have different effects on the Group I peptide. Thus each class of binding agent is not an obvious variant of the other. Present Claim 12, 14, 16 and 19 relate to an extremely large number of possible compounds/products. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. A search for one of the claimed inventions is not likely to result in finding art pertinent to the other inventions, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Should applicant elect any of Groups I-VII, a species restriction is required. Claims 1, 2, 10, 11, 20 and 21 are generic to a plurality of disclosed patentably distinct species comprising an isolated polypeptide or fragment thereof, specifically:

a) an amino acid sequence shown in SEQ ID NO:2,

b) an amino acid sequence of an allelic variant of an amino acid sequence shown in SEQ ID NO:2, and an amino acid sequence of an ortholog (derived from another organism) of an amino acid sequence shown in SEQ ID NO:2,

c) a fragment of an amino acid sequence shown in SEQ ID NO:2; wherein said fragment comprises at least 10 contiguous amino acids, or

d) an isolated human kinase polypeptide sequence having at least 70% homology with an amino acid sequence shown in SEQ ID NO:2, and an isolated human kinase polypeptide sequence having at least 90% homology with an amino acid sequence shown in SEQ ID NO:2.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In the instant case, each specie is a distinct invention, since they are not disclosed as used together, and each has distinct amino acid sequences such that they possess different structures that can lead to different functions and effects. For example, since the amino acid sequence from Group IIa is different from Group IIc, these differences would result in different tertiary structure and function that would be unique from each other. It is possible to synthesize a polypeptide fragment of up to 100 amino acids *ex vivo* that would satisfy the individual requirements of Groups IIc and IId, respectively. However, expression of a nucleic acid encoding the Group IIa full-length polypeptide whose amino acid sequence is shown in SEQ ID NO:2 requires a host cell, and thus the synthesis of these two polypeptides can be materially different. The basis for distinction between the Group IIa and Group IIb polypeptides is determined by the nucleic acid encoding the allelic variants or orthologs claimed in Group IIb. The nucleic acid encodes the amino acid sequence of the polypeptide. Although the nucleic acids encoding the allelic variant or ortholog of the Group IIa polypeptide may retain the ability to hybridize to the nucleic acid molecules shown in SEQ ID NOS: 1 or 3 under stringent conditions, the resulting amino acid

sequence may well be different, resulting in different tertiary structure and function that would be unique from the Group IIa polypeptide. It would be an undue burden to search for the varying combinations of all possible nucleic acid sequences, full-length or fragments thereof, capable of hybridizing to the nucleic acid molecules shown in SEQ ID NOS: 1 or 3 under stringent conditions. Similarly, it would be an undue burden to search for the varying combinations of all possible amino acid sequences, full-length or fragments thereof, yielding at least 70% homology to the full-length polypeptide of SEQ ID NO:2.

Because these inventions are structurally distinct for reasons given above, and because a search of one does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER